



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/630,883

07/30/2003

Seth A. Foerster

END-897DIV2

7937

21884 7590 06/19/2008

WELSH & FLAXMAN LLC
2000 DUKE STREET, SUITE 100
ALEXANDRIA, VA 22314

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,883	Applicant(s) FOERSTER ET AL.	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claims 46 and 51 are objected to because of the following informalities: Both claims have been amended to read “the mass is introduction”, which is grammatically incorrect. The phrase should read as “the mass is introduced”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 46-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (4,832,686).

Anderson discloses a bioabsorbable means for applying a therapeutic agent to a biopsy site and further disclose a mass of material that is detectable by at least two imaging detection methods when introduced into the cavity site created when the tissue has been removed; the mass remains at the site for at least a first time period after the introduction into the cavity site created when tissue has been removed and does not interfere with imaging during a second time period after the first time period; the mass remains imageable for the first time period and clears from the site during the second time period; and the marker is detectable by at least two of the following imaging

methods: MRI, ultrasound, x-ray, mammography or fluoroscopy. See Column 4, lines 8-33; and Column 7, lines 4 and 41-51.

The disclosure of a radiopaque marker inherently discloses the ability to remotely image the marker using x-ray and/or fluoroscopy. Furthermore, the ability of the material to degrade in a specified period of time would also inherently disclose the ability to image the site for a first predetermined time and not interfere with imaging during a second time period.

Response to Arguments

4. Applicant's arguments filed March 21, 2008 have been fully considered but they are not persuasive.

The Applicants argue Anderson fails to provide teaching of a detectable mass of material that remains detectable at the cavity site of a first period of time and does not interfere with imaging of tissue after the first period of time. Anderson clearly discloses the use of biodegradable polymers such as polylactic acid for the body of the degradable element. This material is well known in the art to provide a device that remains at an implantation site for a predetermined period of time before it begins to degrade and finally dissipate from the implantation site. Furthermore, Anderson clearly discloses the application of "other materials" in addition to the polylactic acid, and further discloses "radiopaque markers". Due to the disclosure in Anderson, utilizing "other materials", which comprise chemotherapeutic agents, antibiotics, and hemostatic agents, one of ordinary skill in the art would have utilized a radiopaque substance and

not individual markers, due to the fact that the individual markers would have to be uniformly dispersed within the polylactic acid matrix forming the bioabsorbable marker. Furthermore, one of ordinary skill in the art would have been able to recognize the fact that once the biodegradable matrix has been fully degraded, the radiopaque components would not be concentrated within a single area, and therefore would inherently be dispersed throughout the body, therefore creating a period of time that allows tissue to be imaged without interference.

The Applicants further argue Anderson fails to teach a bioerodible radiopaque material. The current specification is clearly silent with respect to a bioerodible radiopaque material. The only support is found for a biodegradable marker that is imageable. Therefore the radiopaque material itself is not degradable, but the carrier matrix of the marker is degradable.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., bioerodible radiopaque material) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Patent Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736